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| 10/550,671 | 11/09/2005 | Hideaki Yamaoka | TOYA114.007APC | 1379 |

20995 7590 03/28/2008
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| EXAMINER |
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LONG, SCOTT

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| ART UNIT | PAPER NUMBER |
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1633

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| NOTIFICATION DATE | DELIVERY MODE |
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03/28/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcarter@kmob.com
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| <p align="center">Advisory Action Before the Filing of an Appeal Brief</p> | <p>Application No. 10/550,671</p> | <p>Applicant(s) YAMAOKA ET AL.</p> | |
| | <p>Examiner Scott D. Long</p> | <p>Art Unit 1633</p> | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 February 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633

Continuation of 11. does NOT place the application in condition for allowance because:

The applicant presents the following argument: GDH activity obtained with the claimed invention was unexpectedly high which could not have been predicted based upon the combination of references (Remarks, page 2, parag. 3). Specifically, the applicant asserts "unexpected results were obtained with the claimed combination compared to the prior art...a 23 fold increase...in GDH activity in the presence of the ccm system in E.coli versus production in Burkholderia cepacia KS1 strain." (page 3, 3rd parag.).

Instant claim 1 is directed to an Escherichia bacterium comprising GDH subunits and ccm operon, thereby enhancing expression of a ccm system. instant claim 6 is directed to a method for producing a GDH complex, wherein the GDH subunits are expressed. The specification teaches that the phrase "expression of the ccm system is enhanced" means that the expression is enhanced compared with that in a wild strain or unmodified strain of Escherichia bacteria or that a modification is made so that the system can be expressed even under conditions which are not the anaerobic and special conditions. (page 9, lines 2-8). The specification further teaches, "To enhance the expression of the ccm system, genes of the ccm operon can be ligated to a promoter that constitutively expresses them or a promoter that can regulate their expressions, and the obtained recombinant gene can be introduced into an Escherichia bacterium." (page 9, parag.2). According to the teachings of the specification, any Escherichia bacterium that comprises a ccm operon which can express the ccm system under aerobic culture conditions would satisfy the limitation of "expression of the ccm system is enhanced." Because the combination of Sode, Herbaud and Arslan teach these limitations, the examiner believes the combination satisfies the requirement of "enhanced" expression. In particular, Herbaud et al. teach E.coli comprising plasmid pEC86 (containing the ccm operon) and indicates that alpha and beta subunits of ccm are produced when this transformed Escherichia is cultured under aerobic conditions (pages 20- 21), thereby satisfying the limitations of the instant claims directed to "enhanced expression".

In addition, the examiner notes that the applicant's arguments directed to unexpected production levels of 23 fold production, unpersuasive because these limitations are not in the claims and the definition of "enhanced expression" as defined by the specification do not require such levels.

Therefore, the examiner finds the applicant's arguments unpersuasive and hereby maintains the rejection of the instant claims for the reasons of record. No claims are allowed. .